UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

OUTSOURCING FACILITIES ASSOCIATION, ET AL.,

Plaintiffs,

v. **No. 4:25-cv-0174-P**

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants.

OPINION & ORDER

Before the Court are Plaintiffs Outsourcing Facilities Association's and North American Custom Laboratories LLC Partners' (collectively "Plaintiffs") Motion for Summary Judgment (ECF No. 70); Defendants Dr. Robert M. Califf's and the United States Food and Drug Administration's (collectively, the "FDA") Motion for Summary Judgment (ECF No. 68); and Intervenor Defendant Novo Nordisk Inc.'s ("Novo") (collectively with the FDA, the "FDA Defendants") Motion for Summary Judgment (ECF No. 72). Having considered the briefing, record, and applicable legal authorities, the Court will **DENY** Plaintiffs' Motion and **GRANT** the FDA Defendants' Motions.

BACKGROUND

The Court's previous orders in this case and the companion case thoroughly discuss the statutory and regulatory background, and the Court will not repeat it here. *Outsourcing Facilities Ass'n v. U.S. Food & Drug Admin.* (hereinafter "*OFA I*"), No. 4:24-CV-0953-P, 2025 WL 746028, at *1–2 (N.D. Tex. Mar. 5, 2025) (Pittman, J.); *Outsourcing Facilities Ass'n v. U.S. Food & Drug Admin.* (hereinafter "*OFA II*"), No. 4:25-CV-0174-P, 2025 WL 1239727, at *1–2 (N.D. Tex. Apr. 24, 2025) (Pittman, J.). Thus, the following is a brief recitation of the relevant procedural history of this case.

Plaintiffs filed this case on February 24, 2025, challenging the FDA's removal of Ozempic® and Wegovy® (collectively, the "Novo Drugs") from the shortage list. The FDA removed the Novo Drugs from the shortage list on February 21, 2025, when it issued its opinion (hereinafter, the "Delisting Action"). Subsequently, on March 4, 2025, Novo filed its Motion to Intervene, which the Court granted on March 5, 2025. On March 20, 2025, Plaintiffs filed their Motion for Preliminary Injunction and stay, which the Court denied on March 24, 2025. The Court placed the Parties on a briefing schedule for their respective Motions for Summary Judgment. Those Motions have been briefed and are ripe for consideration.

LEGAL STANDARD

In a case challenging an agency action under the Administrative Procedure Act ("APA"), summary judgment "serves as the mechanism for deciding" whether the action "is supported by the administrative record and otherwise consistent with the APA standard of review." *Gadhave v. Thompson*, No. 3:21-cv-2938-D, 2023 WL 6931334, at *1 (N.D. Tex. Oct. 19, 2023) (citation omitted). The agency resolves "factual issues to arrive at a decision supported by the administrative record." *Yogi Metals Grp. Inc. v. Garland*, 567 F. Supp. 3d 793, 797–98 (S.D. Tex. 2021), *aff'd,* 38 F.4th 455 (5th Cir. 2022) (citation omitted). The district court then applies the APA standards of review to determine whether, as a matter of law, "the evidence in the administrative record permitted the agency to make the decision it did." *MRC Energy Co. v. U.S. Citizenship & Immigr. Servs.*, No. 3:19-cv-2003-K, 2021 WL 1209188, at *3 (N.D. Tex. Mar. 31, 2021) (citation omitted). The entire case is thus a question of law, with the district court sitting as an appellate tribunal. *Id.* at *3.

ANALYSIS

Plaintiffs' Complaint raises six claims. *See generally* ECF No. 1. Those claims are: (1) rulemaking without conducting notice and comment; (2) failure to consider the statutory factors; (3) facially contradictory findings that undermine the basis of the agency action; (4) failure to consider countervailing evidence; (5) unlawful

interpretation of the statute under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024); and (6) failure to publish a rule in the federal registry. *Id.* at 14–20. In their respective Motions, the Parties each contend they are entitled to summary judgment on all of Plaintiffs' claims. ECF Nos. 68, 70, 72. Because claims one and six are both predicated on the premise that the Delisting Action is a rule, the Court considers them together. The Court will then address Plaintiffs' unlawful-interpretation claim. And finally, the Court concludes with Plaintiffs' arbitrary-and-capricious claims.

A. Notice-and-Comment and Failure to Publish Claims

Plaintiffs' first and sixth claims are predicated on the Delisting Action being a substantive rule. Plaintiffs assert that the Delisting Action is a substantive rule that the FDA should have issued in compliance with the APA's stringent notice-and-comment requirements. In contrast, the FDA Defendants argue that the Delisting Action was properly issued through adjudication.

As Plaintiffs state in their Motion, the arguments raised on this issue have been previously addressed by this Court three times. *OFA I*, 2025 WL 746028, at *4–8; *OFA I*, 2025 WL 1397537, at *2 (N.D. Tex. May 13, 2025) (Pittman, J.); *OFA II*, 2025 WL 1239727, at *4. Thus, the Court has already thoroughly analyzed and decided this issue. The United States Court of Appeals for the Fifth Circuit has suggested it agrees with that determination. *See Outsourcing Facilities Ass'n, v. U.S. Food and Drug Admin.,* No. 25-10385 at ECF No. 98-1 ("For substantially the reasons given by the district court in its thorough opinion explaining its denial of a preliminary injunction, we find that Plaintiffs-Appellants have not made their 'clear showing.'"). The Court fully adopts that reasoning and conclusion here and finds that the Delisting Action is not a rule and was thus properly promulgated through adjudication. Therefore, Plaintiffs' Motion is **DENIED,** and the FDA Defendants' Motions are **GRANTED** on claims one and six.

B. Unlawful Interpretation Claim

Plaintiffs' fifth claim is based on their assertion that the FDA did not comply with "the best reading of the statute" as required by *Loper*

Bright. ECF Nos. 1 at 18–20; 71 at 21–22. Similar to above, as Plaintiffs acknowledge in their Motion, the Court has previously addressed Plaintiffs' arguments on this claim. ECF No. 71 at 21; *OFA I*, 2025 WL 1397537, at *2–5. Thus, the Court has already thoroughly analyzed and decided this issue. The Court fully adopts that reasoning and conclusion here and holds that the FDA correctly applied the statute when issuing the Delisting Action. Therefore, Plaintiffs' Motion is **DENIED,** and the FDA Defendants' Motions are **GRANTED** on claim five.

C. Arbitrary and Capricious Claims

The Court now turns to Plaintiffs' second, third, and fourth claims which assert that the Delisting Action was arbitrary and capricious. Agency decisions are "presumptively valid; the [plaintiff] bears the burden of showing otherwise." *Barr v. SEC*, 114 F.4th 441, 447 (5th Cir. 2024); *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 120 F.4th 494, 504 (5th Cir. 2024) (citation modified). "If the agency articulates a rational relationship between the facts found and the choice made it does not act arbitrarily or capriciously." *Joseph v. Dir. of Tex. Serv. Ctr., U.S. Citizenship & Immigr. Servs.*, No. 24-40249, 2025 WL 458001, at *3 (5th Cir. Feb. 11, 2025) (quoting *Louisiana ex rel. Guste v. Verity*, 853 F.2d 322, 327 (5th Cir. 1988)). The "focal point" of that review "should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). And "[j]udicial review under that standard is deferential, a[s] a court may not substitute its own policy judgment for that of the agency." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). While courts "may not supply a reasoned basis for the agency's action that the agency itself has not given," courts are to "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Tex. Med. Ass'n,* 120 F.4th at 504 (citing *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983)).

Here, Plaintiffs assert that the Delisting Action is arbitrary and capricious because: (1) the FDA failed to accurately account for compounding supply in its demand projection; (2) the FDA failed to address a Novo Executive's statement; (3) Novo lacked sufficient supply

even without accounting for compounding; and (4) the FDA improperly ignored countervailing evidence. *See* ECF No. 71 at 8–21.

1. Compounding Supply

Plaintiffs argue the Delisting Action was arbitrary and capricious because the FDA completely ignored that Novo "itself estimated that 20% of the market was satisfied by compounders" and "it could satisfy, at best, [redacted]." ECF No. 71 at 9. A review of the record reveals that Plaintiffs misread[1] the very statements they cite to. *First*, the FDA asked Novo about the 20% estimate. ECF No. 49-2 at 262. *Second*, the 20% estimate comes not from Novo but a CNN article quoting an analyst at a financial firm. *Third*, the estimate deals with compounding of both tirzepatide and semaglutide, so it included drugs not at issue here. *Id. Fourth*, it included unapproved or off-label users. *Id.* And *fifth*, Novo explicitly stated "the 20 percent estimate ***is not an appropriate estimate to project demand*** for Novo Nordisk's approved semaglutide injection products following removal from the Drug Shortage List." *Id.* (emphasis added)

Moreover, Novo estimated that it will be able to [redacted] as Plaintiffs claim. *Id.* at 391. Thus, even if Plaintiffs were right that the FDA had to apply a 1:1 demand increase for the 20% estimate—which they are not—the record demonstrates [redacted].

2. The Novo Executive's statement

Plaintiffs next ask the Court to "vacate and remand the Decision to afford the FDA the opportunity to address" two statements made by Novo's CEO in a November 2024 interview with Reuters. ECF No. 71 at 10–11. Specifically, Plaintiffs emphasize that the Delisting Action fails to evaluate two statements made by Novo's CEO in that interview: (1) that "there are far more patients who would like to have the

[1]In cases where such mistakes can be attributed to either an accidental misread or an intentional mischaracterization, the Court prefers to attribute them to accident rather than malice. However, Plaintiffs' consistent and pervasive pattern of similar mistakes, in this case and *OFA I*, has made it increasingly difficult for the Court to assume they are the product of accident.

treatment than what both Lilly and we can supply" (ECF No. 49-2 at 262); and (2) "we'll also see more volumes going into the U.S. market because we see an intact demand there, and we're far from saturating that demand." *Id.* As a preliminary matter, in the Delisting Action the FDA was not "required to discuss each and every piece of evidence or write an exegesis on every contention." *Kurshumi v. Ashcroft*, 102 F. App'x 172, 175 (1st Cir. 2004); *see also Deep v. Barr*, 967 F.3d 498, 503 (5th Cir. 2020); *also Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993) (Agencies need not "discuss every item of fact or opinion included in the submissions" they receive). Thus, the omission of the CEO's statements from the Delisting Action is not dispositive in the arbitrary analysis.

Plaintiffs claim the FDA erred by failing to evaluate these statements. ECF No. 71 at 11. However, the very record cited by Plaintiffs shows the FDA was aware of the comments and concerned about them. ECF No. 49-2 at 262 (the FDA asking Novo about these statements and what they mean with regard to the availability of the Novo Drugs in the United States). Novo responded to that inquiry by explaining the first statement refers to the global market for both the Novo Drugs and the Lilly Drugs—not just the Novo Drugs in the United States. *Id.* Further, Novo provided that the second statement "refers generally to the need for diabetes and obesity treatments, not the specific demand for" the Novo Drugs. *Id.* Novo then continued its response by referring to the detailed data it provided to demonstrate that supply is outpacing demand in the United States market. *Id.* at 262–63. Because the FDA did not simply ignore the comments but rather confronted Novo with them, the Court holds that Plaintiffs failed to demonstrate that it was arbitrary for the FDA to give more weight to data and other detailed evidence than to two statements by Novo's CEO in early November 2024 that are seemingly taken out of context.

3. Other Arguments

Next, Plaintiffs assert the FDA "acted arbitrarily in ratifying [Novo]'s assertions" because: (1) Novo [redacted]; (2) the FDA's demand calculation was [redacted];

(3) Novo's inventory data is confusing and opaque;[2] and (4) the Delisting Action does not adequately explain the choice of time period. ECF No. 71 at 11. Plaintiffs raised the first three arguments at the preliminary-injunction stage, and they provide no new evidence to support them now. *Compare* ECF No. 37 at 6–16, *with* ECF No. 71 at 11–17. The Court thoroughly addressed the first three arguments in its order of the Motion for Preliminary Injunction. *OFA II*, 2025 WL 1239727 at *4–7. The Court fully incorporates and adopts that reasoning and conclusion here. Thus, the Court will address only Plaintiffs' new argument—the Delisting Action does not adequately explain the choice of time period.

Plaintiffs argue that the Delisting Action is arbitrary because the FDA stated that it "needed 'older data'" for its determination in *OFA I* but chose a shorter time period here. ECF No. 71 at 17–18. Plaintiffs cite to *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009) for the proposition that an agency must provide reasoned explanation for why "it is changing position." *Id.* at 515. Plaintiffs argue, as they did in *OFA I*, that the only explanation is the FDA arbitrarily delegated its authority. This argument fails for three reasons. *First*, Plaintiffs—flip flopping their own position—misquote the FDA.[3] In *OFA I*, the FDA stated that it "*permissibly* considered older data." *OFA I*, ECF No. 150 at 6 (emphasis added). *Second*, just as in *OFA I*, the record does not support the assertion that the FDA allowed Novo to choose the time period. *See, e.g.*, ECF No. 49-2 at 377 ("FDA Question 2a[:] Please provide the [redacted] for each strength for each of Ozempic and Wegovy."), 380 ("FDA Question 2d[:] Please provide the [redacted] for each strength for each of Ozempic and Wegovy.").

[2]Despite the Court and the FDA Defendants previously explaining Plaintiffs' misreading of Tables 2 and 5 (*See OFA I*, 2025 WL 1239727 at *6), Plaintiffs once again emphasize that misreading. The Court refers Plaintiffs to FN 1.

[3]*See* FN 1.

And *third*, the FDA's choice to exercise its discretion in selecting a time period was not a "depart[ure] from a prior policy" or a "disregard [for] rules that [were] still on the books." *Fox Television Stations, Inc.*, 556 U.S. at 515. In fact, the FDA's choice to evaluate a different time period than *OFA I* bolsters the Court's decision that the Delisting Actions did "not promulgate a new policy-type rule or standard that will govern the FDA's future actions" but rather "made a specific factual determination based on the statutory definition of shortage." *See OFA I*, 2025 WL 746028, at *8. Here, the FDA chose a time period that is consistent with the statutory mandate and made a determination on whether supply exceeds demand. It did not "depart from a prior policy" established in *OFA I* because *OFA I* did not establish a policy.

4. Countervailing evidence

Finally, Plaintiffs assert the Delisting Action "handwaved hundreds of pages of administrative record evidence" with "an almost breathtaking lack of evenhandedness." ECF No. 71 at 18. Plaintiffs point to the following evidence to demonstrate the arbitrary nature of the FDA's "handwav[ing]": (1) a chart created by Plaintiffs for the purposes of this litigation; (2) website screen shots from [redacted]; (3) reports created by Hims and Hers for multiple drugs; and (4) letters from themselves and the Alliance for Pharmacy Compounding regarding compounding estimates. *Id.* at 18–19. Because the Court assumes Plaintiffs pointed out what they view as their best evidence, the Court will address each.

First, Plaintiffs cite to a ten-page chart they created for this litigation. *Id.* at 18 (citing to ECF No. 39-1 at 238–48). Plaintiffs' chart is not in the administrative record. Thus, it was not before the FDA when it made its determination. Accordingly, the Court finds it was not arbitrary for the FDA to not consider a chart that was not before it.

Second, Plaintiffs cite to a series of screen shots taken in [redacted] of wholesalers' websites. ECF No. 71 at 19. Plaintiffs argue the FDA should have requested more information about the screen shots and that they evidence a nationwide shortage. *Id.* at 20. "The APA imposes no general obligation on agencies to conduct or commission

their own empirical or statistical studies." *Fed. Commc'ns Comm'n v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021). In the Delisting Action, the FDA discussed this evidence and explained that these "individual 'snapshots' in time" "do not undermine or outweigh the comprehensive information provided by Novo . . . ." ECF No. 49-2 at 39–40. The Court has addressed this issue and found that "[i]t is not unreasonable for the FDA to consider detailed and comprehensive evidence to be more persuasive than website screen shots, some of which were undated." *OFA II*, 2025 WL 1239727 at *8. The Court's prior decision has only been bolstered by its review of the administrative record. Thus, the Court determines that the FDA's decision to give more weight to detailed and comprehensive evidence rather than website screen shots, was not unreasonable in light of the evidence before it.

Third, Plaintiffs point the Court to the Hims and Hers reports. ECF No. 71 at 19. The Hims and Hers report were constructed based on a survey that was posted on their respective websites. *See* ECF No. 49-5 at 1528. The surveys involved both tirzepatide and semaglutide products. *See id.* at 1529. And the issues with these very surveys have been identified by the FDA and previously discussed by this Court. *See OFA I*, 2025 WL 746028 at * 13 ("(1) there is no way to verify how many individuals actually filled out the reports, when they filled out the reports, or when their inability to obtain the drugs occurred; (2) the prompt does not define 'inability to access' so some may be reporting that a pharmacy was out of stock and others that their doctor did not prescribe them the medication."). Plaintiffs have not provided the Court with any additional or new evidence which changes its prior determination that it was not unreasonable for the FDA to give less weight to this survey data. Thus, the Court again finds the same here.

Fourth, and finally, Plaintiffs assert the FDA arbitrarily ignored their letter which estimated that [redacted] were being filled by compounders. ECF No. 71 at 20. Further, Plaintiffs claim the FDA did not give sufficient weight to the Alliance for Pharmacy Compounding letter (hereinafter "APC letter"). *Id.* at 19–20. Beginning with the APC letter, in the Delisting Action, the FDA (despite questioning whether all doses were for approved uses) fully accepted the

APC letter's compounding volume estimate. ECF No. 49-2 at 44 ("we assume for the purposes of this decision that the quantities reported by APC are accurate and add them to the quantities reported by outsourcing facilities . . . ."). Therefore, the FDA's treatment of the APC letter was not arbitrary.

Turning to the Plaintiffs' letter, it is undisputed that the letter's estimate is not mentioned in the Delisting Action. However, the FDA's failure to explicitly discuss the letter in the Delisting Action does not make the decision arbitrary. Plaintiffs' letter, without citing a single source or providing any empirical data, simply states that compounding makes up fifty percent of the market. ECF No. 49-4 at 113–14. In contrast, the Delisting Action discusses the reporting requirements that compounders are subject to and the data provided by that reporting. ECF No. 49-2 at 41–46. The FDA then added the estimated compounding number from the APC letter to the reported data. *Id.* at 44. It was thus not unreasonable for the FDA not to credit an unsupported estimate that was far afield from what the actual data showed. And the FDA was not "required to discuss each and every piece of evidence or write an exegesis on every contention." *Kurshumi*, 102 F. App'x at 175; *see also Deep* 967 F.3d at 503. Consequently, the Court finds the FDA did not violate the APA by giving more weight to specific, reliable, comprehensive, and current information obtained through mandatory reporting than unsupported estimates from Plaintiffs. Accordingly, the Court will **DENY** Plaintiffs' Motion for Summary Judgment and **GRANT** the FDA Defendants' Motions for Summary Judgment as to these claims.

CONCLUSION

For the reasons set out above, Plaintiffs' Motion for Summary Judgment is **DENIED**, and the FDA Defendants' Motions for Summary Judgment are **GRANTED**.

Given the agreed confidentiality agreement that was entered into by the Parties, and enforced by the Court, the undersigned finds it appropriate to file this unredacted opinion under seal. Shortly after the opinion is filed, the Parties will be provided, via email, an unsigned PDF

version of the order. It is **ORDERED** that, **on or before 4:00 p.m., June 18, 2025**, the Parties shall submit, via response to the email, an agreed upon version of the order containing any appropriate redactions. After receiving and reviewing the Parties' version, the Court will issue the redacted order.

SO ORDERED on this **13th day of June 2025.**

Mark T. Pittman

MARK T. PITTMAN
UNITED STATES DISTRICT JUDGE